The following information was submitted on 12/31/2006:

Name & Sponsoring Organization

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Are you submitting comments on behalf of a sponsoring organization? Yes
If yes, please enter the name of the organization: The Center for Regulatory Effectiveness

Comments and Questions

1. Do you have comments on the priority areas for the development and validation of alternative test methods listed above?

   CRE COMMENTS ON NICEATM/ICCVAM 5-YEAR PLAN Submitted December 31, 2006 by web site http://iccvam.niehs.nih.gov/docs/5yearplan.htm and by e-mail 5yearplan@niehs.nih.gov The Center for Regulatory Effectiveness appreciates the opportunity to submit these preliminary comments on the development of a 5-Year Plan for NICEATM/ICCVAM. Our first comment is a question: who is actually developing the Plan? The answer to this question is not clear to us from the Federal Register notice soliciting public comment. Also, is Dr. William S. Stokes the designated contact for any questions about the Plan? We would next like to comment on the questions HHS/NIH/NIEHS asked in their Federal Register notice of the Plan. The notice identified 9 specific types of regulatory safety tests. With regard to these tests, the agencies ask: 1. Do you have comments on the priority areas for the development and validation of alternative test methods listed above? 2. Considering available science and technology, what development, translation, and validation activities are most likely to have the greatest impacts within the next five years on refining, reducing, or replacing animal use? 3. What research and development activities hold the greatest promise in the long-term for refining, reducing, or replacing animal use? 4. What are appropriate measures for evaluating progress in enhancing the development and use of alternative test methods? 71 FR 66172 (Nov. 13, 2006). With regard to all these questions, we recommend that the agencies ensure that development of any of these tests meet the applicable Information Quality Act standards. The IQA is codified at 44 U.S.C. §§ 3516 et seq. The agencies comprising NICEATM/ICCVAM have published their own individual IQA Guidelines. If any of the tests developed by NICEATM/ICCVAM do not meet IQA requirements, then no federal agency can use or rely on the tests. In order not to waste time and scarce resources, the agencies should always ensure that any test method meets IQA standards. Consequently, the Plan should expressly state that NICEATM/ICCVAM tests will be developed in accordance with the IQA requirements. The Plan should also outline the process that will be used to ensure compliance. With regard to the compliance process, the Plan should state which IQA guidelines will apply during development of NICEATM/ICCVAM tests. There are 15 different member agencies. The agencies individual IQA guidelines are not identical. We recommend that NICEATM/ICCVAM apply the most rigorous of its member agencies IQA guidelines. We also recommend that public comment be requested on the agencies proposed choice of governing IQA guidelines. We also note that the NICEATM/ICCVAM website listing relevant regulations and guidelines does not include the IQA and the agency IQA guidelines. We request that this website be corrected to include references and links to the IQA and IQA guidelines. In addition to including the IQA, the Plan and the web site

should include links and references to the National Technology Transfer Advancement Act of 1995 (Tech Transfer Act), 15 U.S.C. § 272 note. The NICEATM/ICCVAM web site, under the title Relevant Regulations, Guidelines and Laws, contains numerous references and links to International Regulations and Guidelines. If the foreign entities promulgating these regulations or guidelines are developing tests like those being developed by NICEATM/ICCVAM, then the Tech Transfer Act may require that NICEATM/ICCVAM consult with them during its own development of tests. Similarly, the Tech Transfer Act may require that NICEATM/ICCVAM use the tests developed by these foreign entities, unless to do so would be inconsistent with applicable law or otherwise impracticable. If, hypothetically, NICEATM/ICCVAM ultimately decides not to use similar tests developed by these foreign entities, then the Tech Transfer Act may require that NICEATM/ICCVAM notify OMB in advance of adopting different tests. NICEATM/ICCVAM may also have to explain why it is not using the tests adopted by the foreign entities. For the readers convenience, the relevant text of the Tech Transfer Act is set forth below: 1) In general.--Except as provided in paragraph (3) of this subsection, all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments. "(2) Consultation; participation.--In carrying out paragraph (1) of this subsection, Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate with such bodies in the development of technical standards. "(3) Exception.--If compliance with paragraph (1) of this subsection is inconsistent with applicable law or otherwise impractical, a Federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of each such agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards. Each year, beginning with fiscal year 1997, the Office of Management and Budget shall transmit to Congress and its committees a report summarizing all explanations received in the preceding year under this paragraph. 15 U.S.C. § 272 note. We thank you for the opportunity to submit these preliminary comments. If you have any questions, please contact Scott Slaughter, The Center for Regulatory Effectiveness, 11 DuPont Circle, NW, Suite 700, Washington, D.C. 20036, Telephone 202/265-2383, slaughter@mbsdc.com. Sincerely, Scott Slaughter The Center for Regulatory Effectiveness

2. Considering available science and technology, what development, translation, and validation activities are most likely to have the greatest impacts within the next five years on refining, reducing, or replacing animal use?

   Not Provided.

3. What research and development activities hold the greatest promise in the long-term for refining, reducing, or replacing animal use?

   Not Provided.

4. What are appropriate measures for evaluating progress in enhancing the development and use of alternative test methods?

   Not Provided.